K100449

APR 23 2010

510(k) Summary
510(k) Number

MinXray, Inc.
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Northbrook, Illinois 60062, USA
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Date Prepared: February 4, 2010
Contact: Keith Kretchmer, President

1. **Identification of the Device:**
   Proprietary-Trade Name: CMDR-2S Digital Diagnostic X-Ray System (Mobile)

2. **Classification Name:** Mobile x-ray system, Product Code 90 IZL and Solid State X-Ray Imager (Flat Panel/Digital Imager) 90 MQB, Picture Archiving and Communications System 90 LLZ.

   Common/Usual Name: Digital Mobile Diagnostic X-Ray System

3. **Equivalent legally marketed devices**: MinXray CMDR-1S, K082627; DICOMPACS, OEHM UND REHBEIN GMBH K091364; CPI Rad Vision. CPI Canada, K083224

4. **Indications for Use (intended use)** This digital radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammographic use.

5. **Description of the Device**: This represents the straightforward interconnection of three devices: The MinXray HF120/60H PowerPlus™ (K040046), the Varian Solid State Imager, and the dicomPACS® software package. MinXray HF120/60H PowerPlus™ is a portable unit which operates from 120 V 50-60~ AC. The generator unit utilizes a high frequency inverter and can be mounted to a tripod or support arm. The usual safety precautions regarding the use of x-rays must be observed by the operator. The digital panel features the Varian flat panel technology in a sleek and compact unit. The portable panel provides digital X-ray image capture for a wide range of applications. The lightweight design, generous imaging area, and fast processing times of the detector make it easy to capture high quality diagnostic images for routine diagnosis, as well as challenging trauma and bedside exams. It's a portable solution for a faster, more streamlined approach to digital radiography.

6. **Safety and Effectiveness, comparison to predicate device.** The results of bench testing indicates that the new device is as safe and effective as the predicate devices. Proper system operation is fully verified upon installation.

7. Substantial Equivalence Chart

Characteristic	MinXray CMDR-1S, K082627. Digital Diagnostic X-Ray System (Mobile)	MinXray CMDR-2S Digital Diagnostic X-Ray System (Mobile)
Intended Use:	Intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. Not for mammography	SAME
Configuration	Mobile System	SAME
Computer	Panasonic laptop	Dell laptop
Generator	High Frequency	SAME
Performance Standard	21 CFR 1020.30	SAME
Generator	Uses high frequency generator made by Mikasa X-Ray in Japan. 80 khz.	SAME generator
PACS software	Not included	dicomPACS®
Power Source	120 V 50/60 Hz AC 20 amp	SAME
Digital Panel	CANON CXDI 50G	Varian 4336R

7. Conclusion

After analyzing bench tests, it is the conclusion of MinXray Inc that the CMDR-2S Digital Diagnostic X-Ray System is as safe and effective as the predicate device, have few technological differences, and has no new indications for use, thus rendering it substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

MinXray, Inc.
% Mr. Daniel Kamm, P.E.
Principal Consultant
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APR 23 2010

Re: K100449
Trade/Device Name: CMDR-2S Digital Diagnostic X-Ray Systems (Mobile)
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: February 11, 2010
Received: February 18, 2010

Dear Mr. Kamm:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donald J. St.Pierre
Acting Director
Division of Radiological Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100449

Device Name: CMDR-2S Digital Diagnostic X-Ray System (Mobile)

Indications For Use:
This digital radiographic system is intended for use by a qualified/trained physician or technician on both adult and pediatric subjects for taking diagnostic x-rays. (Not for mammographic use)

Prescription Use X AND/OR Over-The-Counter Use ____.
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, ~~Office of Device Evaluation (ODE)~~ CDRH

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

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